



CAPITAL PROGRAM MANAGEMENT

Capital Projects in Support of Two Gene Therapy Programs

THE NEED

The client requested that Primecore assume leadership of a strategic project which enabled two strategically important programs; one to produce material to support a Gene Therapy Phase III clinical trial and the second to support the production of material to support a Gene Therapy Phase I clinical trial.

THE APPROACH

It was quickly recognized, as with many capital projects which face difficulties, the primary issue lay in poor and incomplete planning of the project. The management of the capital project was a subset of the overall scope for Primecore, which was to provide support with the governance of the two strategic Gene Therapy programs.

The two programs had gotten into difficulty and there was confusion as to the source of the issue. On one hand, it was felt that the poor performance of the capital project was the root cause, while on the other, it was stated that the primary issue was a lack of definition of the requirements, particularly with the critical process requirements.

THE SOLUTION

Primecore's approach was to split the capital scope between the two programs:

- The scope of the capital was split allowing them to be governed separately
- New charters for each project were developed, along with user requirements and basic design scope
- Phase gate reviews were initiated at the end of the Conceptual and Basic design phases
- Primecore project manager was assigned to lead the effort and mentor the team through completion



THE RESULTS

- *The client experienced clarity on its programs and projects after establishing clear end user requirements*
- *This was particularly important for new technology programs such as Gene Therapy since there will be knowledge gaps in the requirements*
- *As these gaps get completed through the course of the program, the requirements become clearer as well*

